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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,592	04/12/2004	Jong Woo Lee	F-8162	2847

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EXAMINER

SCHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/822,592

Applicant(s)

LEE, JONG WOO

Examiner

Laura C. Schell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diaz et al. (US Patent No. 6,908,452) in view of Mann et al. (US Patent No. 5,957,890). Diaz discloses the device substantially as claimed, including a delivery apparatus (Fig. 1a) for medical fluids, comprising: an outer casing (10) including an upper case (Fig. 2b, 26) and a lower case (22); a tubular body (24) having opposed ends (Fig. 2a discloses the opposed ends) connected with one another (Figs. 11a and 12a disclose that the opposed ends of 24 are connected with one another via 24); a projecting holder (Fig. 2a, 20) being disposed centrally of an interior of said outer casing and extending axially between said upper and lower cases (as element 20 is fixedly

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attached to the upper case (attached to portion 18 of upper case) it is therefore considered to be clearly extending upwards in the axial direction from the center of the case, especially since Applicant has not defined the projecting holder as being integrally formed portion of the upper case), about which said tubular body is circumferentially wound (Figs. 2a, 2b, 11a and 12a), a branch conduit (Fig. 3, 82) connectably joining said opposed ends of said tubular body to one another (Fig. 8 discloses that portions (98) of the branch conduit would be connected to the opposite ends of the tubular body), said branch conduit including an injection port for injection of medical fluids (Fig. 13a discloses an injection port (86) being part of the branch conduit), said injection port being exposed to an outside of said upper case (Fig. 13a); and a hose for delivery of the medical fluids extending through said outer casing and connecting to said branch conduit within said outer casing (Fig. 1a discloses a hose (14) with an end (172) that connects to the port as seen in Fig. 13b. Fig. 13b further shows that the narrow nozzle portion of the medical hose, as seen in Fig. 1a, actually extends into the outer case and through to connect at site (132) which is within the outer case as shown in Fig. 13a, and this connects the hose with the branch conduit through the lumen of (130)). Diaz, however, does not disclose that the tubular body is wound to form at least two layers of said tubular body. Mann, however, discloses medical fluid delivery apparatus (Figs. 2-5 and 13) which has a tubular body (30) circumferentially wound around a projecting holder (Fig. 14), in which the tubular body is wound to form at least two layers (Figs. 2 and 3 show that that 30 is would to form two layers depth-wise, and thirteen layers height-wise). Therefore it would have been obvious to one of ordinary skill in the art at

the time of the invention to have modified Diaz, with winding the tubular member at least two times, as taught by Mann, in order to provide more control/restriction of the fluid flow (col. 4, lines 60-65), in addition to the fact that it has been held that the mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193, USPQ 8.

In reference to claim 13, Diaz discloses an intermediate ring being interposed between said upper case and said lower case (the intermediate ring can be the ring-shaped portion of the screw posts in which the screws which connect (20) to (18) are screwed into, as these are between the upper and lower case), allowing an internal volume of said outer casing to be determined by selection of a particular width of said intermediate ring (Fig. 2a).

In reference to claim 14, Diaz discloses axially extending fixing protrusions disposed on said branch-conduit for affixing said branch-conduit; and corresponding axially extending fixing grooves disposed on at least one of said upper case or said lower case, which cooperate with and fix corresponding ones of said fixing protrusions for axially fixing said tubular body within said outer casing; said protrusions and said grooves being disposed within said outer casing. Fig. 8 discloses parallel protrusions which form a groove (close to the arrow of 82) which allows element 20 (which are the corresponding grooves of the part of the upper case) of Fig. 3 to fit within the groove and hence connect to it, wherein 20 is connected to the upper case and the parallel protrusions forming the groove near 82 are part of the branch conduit which connects to

the tubular body, and hence the interconnections allow the tubular body to axially fix the tubular body within the outer case.

In reference to claim 15, Diaz discloses a unidirectional flow injection valve (Figs. 13a and b), in fluid communication with both said injection port and a passageway hole in said upper case (Fig. 1b, 204, 206 and 208; also see col. 21, lines 30-65).

In reference to claim 16, Diaz discloses a press-openable and closeable lid (Fig. 1b, 230) for alternatively opening and closing said passageway hole of said upper case.

In reference to claim 18, Diaz discloses that the tubular body is wound onto said projecting holder in a stretched state (Fig. 2a discloses that 24 is in a stretched state). In reference to claim 19, Diaz discloses a recess groove formed on said branch-conduit, and wherein an affixing member is fixed by applying pressure to said recess groove (Figs. 8 discloses that the portion (98) or the branch conduit has a recess groove and that the affixing member is a portion of (24) which is fixed by applying pressure to the groove, as seen in Figs. 11a and 11b).

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diaz (US Patent No. 6,908,452) in view of Mann et al. (US Patent No. 5,957,890) and further in view of Davis (US Patent No. 3,217,949). Diaz in view of Mann discloses the device substantially as claimed including the lid, however Diaz in view of Mann does not disclose the scored folding line or slot. Davis, however, discloses a press openable and closeable lid (Figs. 5 and 6, 20) that opens and closes over a hole. Davis also discloses that the lid has a scored folding line (Fig. 1, 23) on the exterior side of the lid, and a v-

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shaped slot (Figs. 3 and 5, 23) on the interior side of the lid, and a portion of the lid (Fig. 6, 14) below the scored folding line is affixed to the upper case. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Diaz in view of Mann with the lid of Davis, in order to provide the infusion device with a lid to cover the opening and keep the opening clean from debris.

Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diaz (US Patent No. 6,908,452) in view of Mann et al. (US Patent No. 5,957,890) and further in view of Lee (US Patent No. 6,024,724). Diaz discloses the device substantially as claimed including a recess groove (Fig. 6, groove in which 50 sits). However, Diaz does not disclose expressly a rabbet groove on the recess groove, a projecting ring on the affixing member, an incised interior side of the affixing member or the recess groove being doubly sheathed. Lee discloses a groove (Fig. 6, 262) and a projecting ring (271) on the affixing member. Lee further discloses that the affixing member is of two layers (Fig. 6) and that a portion of the affixing member (262) is incised so as to be elastically reactive (col. 8, lines 54-64). Lee further discloses that the affixing member would allow the groove to be doubly sheathed. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the recess groove of Diaz with the rabbet groove, projecting member and affixing members as taught by Lee in order to provide a very secure seal between the affixing member and the branch conduit.

Response to Arguments

Applicant's arguments with respect to claims 12-22 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER



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